

## REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks is respectfully requested. Upon entry of the present amendment, claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-22 will be pending. Claims 5, 8, 9, 11, 14, and 18 were previously cancelled. In this Remarks section, the Applicant asserts that the Examiner has not established the prima facie case of obviousness because the art, if anything, teaches away from the present invention. Secondly, the Applicant rebuts the prima facie case of obviousness through the submission of Declarations, which establish that an embodiment of the present invention has achieved surprising commercial success and resolves a long-felt need in the medical industry.

### 1. Failure to Establish a Prima Facie Case of Obviousness

Claims 1-4, 6, 7, and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,054,207 to Lazure et al. in view of the Blass et al. Article, the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, U.S Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al. In addition, claims 12, 13, 15-17, 19, and 20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Blass et al. in view of Stevens et al. (1999), Stevens et al. (1997), and Frank, in further view of Lazure, Beckers, and Hendriks. Applicant respectfully traverses these rejections for the reasons presented below.

Independent claim 1, recites an individual packaged solution for use in conjunction with a planned medical procedure on a neonatal infant. The packaged solution includes a cup-shaped container having a cavity defined therein opening to a mouth. A volume of a solution comprising sucrose and water is disposed within the cavity. The solution comprises about 10% to about 50% sucrose, with a remainder of the solution comprising water. A cover is disposed over the mouth and seals the solution within the cavity. The solution and an interior of the container are in an aseptic state.

As enacted, 35 U.S.C. § 103 of the 1952 Patent Act states the following:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. The examiner bears the initial burden to present a prima facie case of obviousness.

It is then left to the applicant to rebut the prima facie case. In re Oetiker, 977 F.2d 1443, 24 USPQ 2d 1443, 1447 (Fed. Cir. 1992). It is generally accepted that the prima facie case of obviousness is established when the Examiner can provide:

1. one or more references
2. that were available to the inventor and
3. that teach
4. a suggestion to combine or modify the references,
5. the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art.

An applicant who is able to prove that the examiner has failed to establish any one of these elements will overcome the examiner's prima facie case of obviousness.

In the present Application, the Applicant has argued unsuccessfully that the Examiner has not adequately established that the cited references teach or suggest the claimed invention and that the proposed combination could have only resulted from the improper use of hindsight.

The Art Teaches Away from the Proposed Combination.

The references cited by the Examiner teach away from the present invention. The Federal Circuit has outlined the boundaries of obviousness in several significant decisions. In one such decision, Lindermann Maschinenfabrik GmbH v. American Hoist & derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984), a patent was filed on a hydraulic scrap shear. Two different shears were common in the industry: one for light to medium gauge metal and one for high gauge metal. The patent disclosed a device that was capable of processing both types of scrap in a single moderately sized device. Even though all of the elements of the device were

admittedly “old” and “well-known” in the scrap industry, the Court concluded that the combined features in a single device were not obvious. Despite the clear desirability and commercial advantages of a single moderately sized scrap shear, the industry continued to process light and medium gauge metal separately from high gauge metal.

Just as in Lindermann, the elements of the claimed invention of the present application have been cobbled together with the use of admittedly old and well-known elements. The Lazure et al. reference was filed in 1976 and the Blass et al. article was submitted for publication in 1989. The Examiner claims that the Applicant’s invention is obvious to one of ordinary skill in the art, and yet is unable to present any suggestion by anyone in the art over the course of 15 years that in any way suggests the proposed modification. For at least 15 years, hospitals and pharmacies have chosen to hand mix analgesic agents, subjecting newborn infants to potentially inconsistent and unsanitary agents. It defies logic to conclude that these skilled health care providers would continue utilizing an inefficient and potentially hazardous process if there was an “obvious” solution.

On page 3, lines 1-8 of the Office Action dated July, 11, 2003, the Examiner asserts that “each of the features of the invention were ‘notoriously old’ and ‘well-known’ and that all that is missing is a single reference which teaches packaging the sucrose solution in the cup-shaped container.” Although this observation is accurate, it is the same situation as in Lindermann. The prior existence of the elements of a claim does not render the claim obvious. The Examiner is correct to point out that a single reference reciting all the elements is not needed and would be a 35 U.S.C. § 102 rejection rather than a 35 U.S.C. § 103 rejection. However, the Examiner’s burden of proof is higher than merely locating each element of the claim somewhere in the prior art. As recited above, the Examiner must present some suggestion to combine or modify the references present in the prior art. The Applicant contends that the Examiner has not met this burden to present a prima facie case of obviousness. Accordingly, the Applicant respectfully requests the Examiner to reconsider the rejection to claims 1-4, 6, 7, 10, 21, and 22.

The Examiner also rejected claims 12, 13, 15-17, 19, and 20 under 35 USC § 103. Independent claims 12 and 17 recite a method for administering a solution for use in conjunction

with a planned medical procedure on a neonatal infant using a solution contained in aseptic single-use containers. The Applicant contends that claims 12 and 17, as well as all claims dependent thereon, are allowable for the same reason as highlighted above in connection with claim 1.

## 2. Rebuttal of Prima Facie Case

Once the examiner has established a prima facie case of obviousness, the burden shifts to the applicant to rebut with objective evidence of nonobviousness. The applicant may present evidence relating to any of the secondary considerations outlined in Graham v. John Deere Co., 381 US 1, 148 USPQ 459 (1966) such as commercial success, fulfilling a long-felt need, failure of others, copying by others, and unexpected results. In addition, later opinions have added additional secondary considerations such as later discovered unexpected properties of the claimed invention, licenses or industry acquiescence, and skepticism prior to invention by those of ordinary skill. In re Mayne, 104 F.3d 1339, 41 USPQ 2d 1451 (Fed. Cir. 1997); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 43 USPQ 2d 1294, 1297 (Fed. Cir. 1997); In re Dow Chem. Co., 837 F.2d 469, 5 USPQ 2d 1529, 1532 (Fed. Cir. 1988).

The Applicant contends that introduction of the present invention into the marketplace has been met with surprising commercial success and resolves a long-felt need in the industry. The Applicant sells an embodiment of the invention disclosed and claimed in the present application under the trademark SWEET-EASE™. A copy of the sales brochure for the SWEET-EASE™ product is attached herewith.

### Surprising Commercial Success

As outlined in the Declaration of Cathy N. Bush, the SWEET-EASE™ product has had surprising commercial success. Ms. Bush compares the SWEET-EASE™ product with the HEEL HUGGER™ product. Both products are disposable, single-use products used on infants and sold by the Applicant. Even though the SWEET-EASE™ product has been in the industry for less than half as long, it achieved approximately six times as many sales in 2003.

Ms. Bush attributes the surprising commercial success of the SWEET-EASE™ product to the fact that it provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry.

#### Long-felt Need

The present invention fulfills a long-felt need in the industry. As described in the Declarations of Don T. Granger, M.D., Neal Guttenberg, M.D., and M. David Yohannan, M.D. ("Physicians' Declarations"), hand-mixing sucrose solutions have been undesirable. Doing so may contaminate the solution, result in wasted time, and the creation of inconsistent solutions. This has been the status of the art for at least 15 years. Accordingly, it is clear that the present invention addresses a problem that has defied solution. The Physicians' Declarations describe the state of the art before introduction of the SWEET-EASE™ product and the long-felt need of neonatologist. The Physicians' Declarations also describe the impact that the SWEET-EASE™ product has had on the medical industry. The attached Physicians' Declarations are merely a small sample of the declarations that the Applicant could provide. It should be noted that the Applicant could produce additional declarations if the Examiner requires additional support.

In light of the above noted secondary considerations in conjunction with the attached supporting declarations, independent claims 1, 12, and 17, as well as all claims dependent thereon, overcome the Examiners rejection based upon 35 USC § 103.

The Examiner rejected 1-4, 6, 7, and 10 under 35 USC § 112, first paragraph for containing new matter. As noted previously, the claims have been amended to remove this objectionable material and reinstate the previously acceptable broader claims. Accordingly, the Applicant requests removal of these rejections.

All objections and rejections have been fully addressed. It is respectfully submitted that the present Application is in condition for allowance and notice of allowance is earnestly solicited.

DALY -- Appln. No.: 09/670,781

Respectfully submitted,

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